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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,469	10/12/2000	Anne Marie Schmidt	0575/55424-A-PCT-US/JPW/J	7726

7590

01/26/2005

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/689,469

Applicant(s)

SCHMIDT ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-60 and 76-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-60 and 76-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/13/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Re: Schmidt *et al*
Priority Date: 16 April 1999

1. The amendment filed 10/29/2004 is acknowledged and entered into the record.
2. Claims 57-60 and 76-78 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4. The Information Disclosure Statement filed 1/3/2005 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 103

5. The rejection of claims 57-60 and 76-78 are maintained for the reasons of record. Applicant argues that the instantly claimed invention is based on the surprising discovery that inhibiting the interaction between RAGE and amphotericin inhibits tumor invasion and further states that the examiner has ignored this point. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. To rebut an argument involving the use of unexpected results or a surprising discovery, applicant must provide factual evidence or support by way of affidavit or declaration, none of which applicant has provided in response to any of the actions mailed regarding the instant rejection. Moreover, in the instant case, applicant has not provided any evidence that disrupting the interaction between amphotericin and

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RAGE for the inhibition of tumor invasion would be an unexpected or surprising discovery. One of ordinary skill in the art would have found this to be obvious given the teachings of Hori *et al* in view of Miki *et al* and Parkkinen *et al* for the reasons previously argued and now reiterated. The motivation to modify comes from the fact that Hori *et al* teach a method similar to that instantly claimed for screening agents that inhibit the interaction between amphotericin and RAGE. Moreover, Hori *et al* teach that amphotericin has been demonstrated by Parkkinen *et al* to be involved in invasive neoplastic lesions. More specifically, Parkkinen *et al* teach that amphotericin is localized to the leading edge of invasive cells and is generally involved in said invasion. Miki *et al* teaches that RAGE is expressed on the surface of RCC cells. Thus taken together, given the fact that it was known that RAGE is the natural receptor of amphotericin, the role of amphotericin in invasive cells, and that RAGE is expressed on the surface of tumor cells, one of ordinary skill in the art would have found sufficient motivation to screen for agents that disrupted the interaction of RAGE and amphotericin for the purpose of preventing invasiveness of cancer cells as claimed. The expectation of success resides in the fact that the method has already been performed and proven successful by Hori *et al*, albeit in a different cell type, but none the less a skilled artisan would have found sufficient motivation to use cancer cells in place of the neuronal cells.

Applicant additionally argues that the cited references teach away from the instantly claimed invention and specifically state that at the time of the invention the role of amphotericin in tumor invasion would not have been speculated to be involved with RAGE. Applicant's arguments have been carefully considered but are not deemed

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persuasive to overcome the rejection of record. Contrary to applicant's assertions, Hori *et al* clearly sets forth a relationship between the involvement of RAGE and amphoterin and even indicates that amphoterin was involved in tumor invasiveness by reciting the work of Parkkinen *et al* (see page 25760).

Therefore the rejection of claims under 35 USC 103(a) as being obvious over Hori *et al* in view of Maki *et al* and Parkkinen *et al* is maintained for the reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Christopher Yaen

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January 19, 2005

A handwritten signature in black ink, appearing to read "Gary Nickol". The signature is fluid and cursive, with a large loop at the end.

GARY NICKOL
PRIMARY EXAMINER